

January 2022

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

**Phoxilium 1.2mmol/l phosphate Solutions for haemodialysis/haemofiltration:
supply of non-UK labelled batches during the Covid-19 Pandemic**

Dear Healthcare Professional,

Summary:

To ensure continuity in supply, Baxter Healthcare Limited has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply multi-lingual packs intended for the French market.

Product Name and MA Number	Active ingredients	UK Product Code	Replacement Product Code	Labelling Language	Batch Numbers
Phoxilium 1.2mmol/l phosphate PL00116/0708	Calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride, potassium chloride, sodium hydrogen carbonate, disodium phosphate	113637	113638	French, German and Dutch	21J2810 21J2811 21J2812

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients.

Please note the following:

- The replacement products are identical to product you will have already been using. The bags are fully compatible with the continuous renal replacement therapy (CRRT) systems on which you currently use Phoxilium.
- The only difference is the languages of the product information. A comparison of the labelling is provided as an annex to this letter. The labels have key similarities to those of the UK approved product:
 - The product name is the same "Phoxilium".
 - The ink colour used to identify the product on the primary and carton labels is the same green as UK Phoxilium
 - The labelling format for presentation of ingredients amounts, chemical formula etc.

- Please ensure the UK Summary of Product Characteristics and package leaflet for Phoxilium are followed. Both documents can be found on the Electronic Medicines Compendium at the following link:
www.medicines.org.uk/emc/product/2140

Alternatively, copies of the Summary of Product Characteristics and package leaflet can be obtained from Baxter Medical Information, details below. Copies of the UK labelling can also be provided.

Do you need to do anything different when it comes to placing an order?

No, you order as you always would, using the normal product code. The substitution will be done behind-the-scenes by Baxter Customer Services, once we receive your order. You just need to make sure you communicate amongst your staff, so that they aware that the product code they receive on the ICU, may be different to what they normally expect.

You will be charged the same as for your normal product code.

Call for reporting

Healthcare professionals are asked to report suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <https://yellowcard.mhra.gov.uk/>, the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#), and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Adverse Events relating to Baxter products can also be reported direct to Baxter Pharmacovigilance on 01635 206360, or by email to vigilanceuk@baxter.com.

Any drug product quality complaints (including suspected defective medicines) relating to Baxter products can be reported directly to the Baxter Country Quality Assurance Team on 01604 704603, or by email to UK_SHS_QA_Complaints@baxter.com.

Company contact point

If you have any questions about this letter or require more information about Phoxilium, please contact Baxter Medical Information on 01635 206345 or email medinfo_uki@baxter.com.

Yours faithfully



Andrew Warburton
Business Unit Head – Acute Therapies
Baxter UK and Ireland

Comparison Table of product labelling - UK vs replacement product

UK Phoxilium
Product code 113637Phoxilium FR/NL/DE language
Product code 113638

UK/IE/MT	PT	ES	C.N 664398.5 OH
Read the package leaflet before use. Sterile and free from bacterial endotoxins. Before use check for leaks. Use only if solution is clear and practically free from particles. For single use only. Discard any unused solution immediately after use. Not for direct infusion: mix both compartments before use. Mix additives before connecting this bag to the extracorporeal circuit. Keep out of the sight and reach of children. Batch No: see "LOT". Expiry date: see "EXP". Read the package leaflet for shelf life of reconstituted product. Store between +4°C - -30°C. Do not refrigerate or freeze. UK: PL 001160708 IE: PA 2239/053001 MT: MA 1277/03001	Consultar o folheto informativo antes de utilizar. Estéril e livre de endotoxinas bacterianas. Verificar fugas. Só utilizar se a solução estiver limpa e isenta de partículas visíveis. Para utilização única. Rejeitar qualquer solução não utilizada imediatamente após utilização. Não utilizar em perfusão direta: misturar ambos os compartimentos antes de usar. Misturar os aditivos antes de ligar este saco ao circuito extracorpóreo. Manter fora da vista e do alcance das crianças. N.º de lote: ver "LOT". Prazo de validade: ver "EXP". Consultar o folheto informativo quanto ao prazo de validade do produto reconstituído. Conservar entre +4°C e +30°C. Não refrigerar ou congelar. Medicamento sujeito a receita médica resrita. 5152653	Leer el prospecto antes de utilizar este medicamento. Estéril y libre de endotoxinas bacterianas. Compruebe si hay fugas. Utilizar solo si la solución está transparente y no se observa prácticamente ninguna partícula. Para un solo uso. Deseche toda solución que no se haya utilizado inmediatamente después de terminado su uso. No utilizar para infusión directa. Antes de usar, mezclar ambos compartimentos. Mezclar los aditivos antes de conectar esta bolsa al circuito extracorpóreo. Mantener fuera de la vista y del alcance de los niños. No. Lote: ver "LOT". Fecha de caducidad: ver "EXP". Para conocer el periodo de validez del producto una vez reconstituido, leer el prospecto. Conservar a una temperatura entre 4°C y 30°C. No refrigerar o congelar. MEDICAMENTO SUJETO A PRESCRIPCIÓN MÉDICA. Uso hospitalario.	

1.2 HPO₄²⁻
mmol/l4 K⁺
mmol/lphoXilium
1.2 mmol/l Phosphate | Fosfato | FosfatoA
250 ml
B
4750 mlSolution for haemodialysis/haemofiltration | Solução para hemodiálise ou hemofiltração |
Solución para hemodíalisis/hemofiltraciónFor intravenous use and/or haemodialysis | Para uso intravenoso e/ou hemodiálise |
Para uso intravenoso y/o hemodíalisis

Each 1000 ml contains | Cada 1000 ml contém | Cada 1000ml contiene:

	A	B
Before reconstitution Antes da reconstituição Antes de la reconstitución		
Calcium chloride Cloreto de cálcio Cloruro de calcio, 2 H ₂ O	3.68 g	
Magnesium chloride Cloreto de magnésio Cloruro de magnesio, 6 H ₂ O	2.44 g	
Sodium chloride Cloreto de sódio Cloruro de sodio		6.44 g
Potassium chloride Cloreto de potássio Cloruro de potasio		0.314 g
Sodium hydrogen carbonate Bicarbonato de sódio Bicarbonato de sodio		2.92 g
Disodium phosphate Fosfato dissódico Fosfato disódico, 2 H ₂ O		0.225 g

Other ingredients | Outros componentes | Otros componentes:

Small compartment A | Compartimento pequeno A |
Compartimento A pequeño: Water for injections, hydrochloric acid (for pH adjustment) | Água para injetáveis, ácido clorídrico (para ajuste do pH) | Agua para preparaciones inyectables, ácido clorhídrico (para ajuste de pH)Large compartment B | Compartimento grande B |
Compartimento B grande: Water for injections, carbon dioxide (for pH adjustment) | Água para injetáveis, dióxido de carbono (para ajuste do pH) | Agua para preparaciones inyectables, dióxido de carbono (para ajuste de pH)

After reconstitution | Após a reconstituição | Después de la reconstitución, A + B

	Ca ²⁺	Mg ²⁺	Na ⁺	Cl ⁻	HCO ₃ ⁻	K ⁺	HPO ₄ ²⁻
mmol/l	1.25	0.6	140	115.9	30	4	1.2

Theoretical osmolality | Osmolaridade teórica | Osmolaridad teórica: 293 mOsm/l

Marketing authorisation holder | Titular da autorização de introdução no mercado | Titular:
IE/MT/PT/ES: Baxter Holding B.V., Kobaalweg 49, 3542 CE Utrecht, Netherlands | Holanda
UK: Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom

ES: Representante Local Autorizado: Baxter, S.L., Polígono Industrial sector 14, C/ Pouet de Camilo nº2, 46394 Ribarroja del Turia, Valencia, España

Baxter

Product No.: 113637

5000 ml

FR LU BE	BE AT	NL BE
Lire la notice avant utilisation. Stérile et exempt d'endotoxines bactériennes. Vérifier l'intégrité de l'emballage avant utilisation. N'utiliser que si la solution est limpide et exempte de particules. A usage unique. Les quantités de solution non utilisées doivent être jetées immédiatement après emploi. Ne pas injecter directement: mélanger les deux compartiments avant utilisation. Mélanger les additifs avant de connecter cette poche au circuit extracorporel. Tenir hors de la vue et de la portée des enfants. Lire la notice concernant la durée de conservation de la solution reconstituée. No. de lot: voir "lot". A utiliser avant: voir "exp". Conserver entre +4°C et +30°C. Ne pas mettre au réfrigérateur. Ne pas congeler. FR: Médicament soumis à prescription hospitalière. Medicament autorisé n°. 34009 394 497 7 7 Exploitant: BAXTER SAS, Immeuble Berlioz, 4 bis rue de la Redoute, 78280 Guyancourt, FRANCE BE: Medicament soumis à prescription médicale BE340916 LU: 200905002/0517084	Packungsbeilage beachten. Steril und frei von bakteriellen Endotoxinen. Vor der Anwendung auf Undichtigkeiten überprüfen. Nur klare und partikelfreie Lösungen verwenden. Nur zum einmaligen Gebrauch. Restlösung umgehend nach Gebrauch verwerfen. Nicht zur direkten Infusion: Vor der Anwendung die beiden Kammern mischen. Zusätze vor dem Anschließen dieses Beutels an den extrakorporalen Kreislauf zumischen. Arzneimittel für Kinder unzugänglich aufbewahren. Bezüglich der Verwendbarkeit der gebrauchsfertigen Lösung beachten Sie bitte die Packungsbeilage. Ch.-B.: siehe "lot". Verwendbar bis: siehe "exp". Phoxilium zwischen +4°C und +30°C lagern. Nicht im Kühlschrank lagern oder einfrieren. AT: Rezept- und apothekenpflichtig Z. Nr. 1-28490 BE: Verschreibungsspflichtig BE340916	Lees voor het gebruik de bijzutter. Steriel en vrij van bacteriële endotoxinen. Voor gebruik op lekken controleren. Niet gebruiken tenzij de oplossing helder is en er nagenoeg geen zwevende deeltjes te zien zijn. Uitsluitend voor eenmalig gebruik. Niet gebruikte vloeistof dient te worden weggegooid. Niet voor directe infusie: Voor gebruik de inhoud van beide compartimenten mengen. Meng toevoegingen vooraleer de zak wordt verbonden met het extracorporele circuit. Buiten het zicht en bereik van kinderen houden. Lees de bijzutter voor de houdbaarheid van het samengevoegde product. Lotnummer: zie "lot". Uiterste gebruiksdatum: zie "exp". Bewaren tussen +4°C en +30°C. Niet in de koelkast of de vriezer bewaren. NL: U.R. RVO 101528 BE: Geneesmiddel op medisch voorschrift. BE340916

1,2 HPO₄²⁻
mmol/l4 K⁺
mmol/lphoXilium
1,2 mmol/l phosphate | Phosphat | fosfaatA
250 ml
B
4750 mlSolution pour hémodialyse/hémofiltration | Hämodialyse-/Hämofiltrationslösung |
Oplossing voor hemodialyse/hemofiltratieVoie intraveineuse et/ou hémodialyse | Intravenöse Anwendung und/oder Hämodialyse |
Voor intraveeneuze toediening en/of hemodialyse

Formule pour 1000 ml | 1000 ml Lösung enthalten | Elke 1000 ml bevat:

	A	B
Avant reconstitution Vor der Mischung Vóór samenvoegen		
Chlorure de calcium Calciumchlorid Calciumchloride, 2 H ₂ O	3.68 g	
Chlorure de magnésium Magnesiumchlorid Magnesiumchloride, 6 H ₂ O	2.44 g	
Chlorure de sodium Natriumchlorid Natriumchloride		6.44 g
Chlorure de potassium Kaliumchlorid Kaliumchloride		0.314 g
Bicarbonate de sodium Natriumhydrogencarbonat Natriumbicarbonaat		2.92 g
Phosphate disodique Natriummonohydrogenphosphat (Ph. Eur.) Dinatriumfosfaat, 2 H ₂ O		0.225 g

Autres composants | Sonstige Bestandteile | Andere stoffen:

Petit compartiment A | Kleine Kammer A | Uit het kleine
compartiment A: Eau pour préparations injectables, acide
chlorhydrique (pour ajustement du pH) | Wasser für Injektionszwecke,
Salzsäure (zur Anpassung des pH-Werts) | Water voor injecties,
zoutzuur (voor pH-aanpassing).Grand compartiment B | Große Kammer B | Uit het grote
compartiment B: Eau pour préparations injectables, dioxyde de
carbone (pour ajustement du pH) | Wasser für Injektionszwecke,
Kohlendioxid (zur Anpassung des pH-Werts) | Water voor injecties,
koolstofdioxide (voor pH-aanpassing).

Après reconstitution | Nach der Zubereitung | Na samenvoegen, A + B

	Ca ²⁺	Mg ²⁺	Na ⁺	Cl ⁻	HCO ₃ ⁻	K ⁺	HPO ₄ ²⁻
mmol/l	1.25	0.6	140	115.9	30	4	1.2

Osmolality théorique | Theoretische Osmolarität | Berekened osmolality: 293 mOsm/l

Titulaire | Pharmazeutische Unternehmer | Farmaceutische vergunninghouder:
Baxter Holding B.V., Kobaalweg 49, 3542CE Utrecht, Niederlande | Nederland | Pays-Bas

RESPECTER LES DOSES PRESCRITES

Liste I - Uniquement sur ordonnance

Baxter

Product No.: 113638

Bag Label - Reverse	UK Phoxilium Product code 113637		Phoxilium FR/NL/DE language Product code 113638																														
	Open seal ↓ Abra o selo ↓ Abrir sello ↓ D0570049 Rev. 2009-12		Ouvrir la soudure pelable ↓ Der Trennnaht öffnen ↓ Open de lasnaad ↓ D0570050 Rev. 2009-12																														
Code Specific Carton Label	<div><div><div>A 250 ml</div><div>B 4750 ml</div></div><div>phoXilium 1.2 mmol/l Phosphate Fosfato Fosfato</div><div>C.N 664998.50H 8 470006 649985</div></div> <div><div>Read the package leaflet before use. Before use check for leaks. Use only if solution is clear and practically free from particles. For single use only. Discard any unused solution immediately after use. Not for direct infusion: mix both compartments before use. Read the package leaflet for shelf life of reconstituted product. Store between +4°C – +30°C. Do not refrigerate or freeze. UK: PL 00116/0708 IE: PA 2299/053/001 MT: MA 1277/03001</div><div>Consultar o folheto informativo antes de utilizar. Verificar fugas. Só utilizar se a solução estiver limpa e isenta de partículas visíveis. Para utilização única. Rejeitar qualquer solução não utilizada imediatamente após utilização. Não utilizar em perfusão direta. Misturar ambos os compartimentos antes de usar. Consultar o folheto informativo quanto ao prazo de validade do produto reconstituído. Conservar entre +4°C e +30°C. Não refrigerar ou congelar. Medicamento sujeito a receita médica restrita. 5192653 C.N 664998.50H Leer el prospecto antes de utilizar este medicamento. Compruebe si hay fugas. Utilizar solo si la solución está transparente y no se observa prácticamente ninguna partícula. Para un solo uso. Deseche toda solución que no se haya utilizado inmediatamente después de terminado su uso. No utilizar para infusión directa. Antes de usar, mezclar ambos compartimentos. Para conocer el periodo de validez del producto una vez reconstituido, leer el prospecto. Conservar a una temperatura entre 4°C y 30°C. No refrigerar o congelar. MEDICAMENTO SUJETO A PRESCRIPCIÓN MÉDICA. Use hospitalario.</div></div> <div><div>Small compartment A Compartimento pequeno A Compartimento A pequeño: Water for injections, hydrochloric acid (for pH adjustment) Água para injetáveis, ácido clorídrico (para ajuste do pH) Agua para preparaciones inyectables, ácido clorídrico (para ajuste de pH)</div><div>Large compartment B Compartimento grande B Compartimento B grande: Water for injections, carbon dioxide (for pH adjustment) Água para injetáveis, dióxido de carbono (para ajuste do pH) Agua para preparaciones inyectables, dióxido de carbono (para ajuste de pH)</div></div> <div><table><tr><th>Ca²⁺</th><th>Mg²⁺</th><th>Na⁺</th><th>Cl⁻</th><th>HCO₃⁻</th><th>K⁺</th><th>HPO₄²⁻</th></tr><tr><td>mmol/l</td><td>1.25</td><td>0.6</td><td>140</td><td>115.9</td><td>30</td><td>4</td><td>1.2</td></tr></table><div>Theoretical osmolality Osmolaridade teórica Osmolaridad teórica: 293 mOsm/l</div></div> <div><div>Product No.: 113637 Batch No N° de lote Lote: Expiry date Prazo de validade Fecha de caducidad: Marketing authorisation holder Titular da autorização de introdução no mercado Titular de la autorización de comercialización: IE/MT/PT/ES: Baxter Holding B.V., Kobaltweg 49, 3542 CE Utrecht, Netherlands Holanda UK: Baxter Healthcare Ltd, Caxton Way, Thelthorpe, Norfolk, IP24 3SE, UK ES: Representante Local Autorizado: Baxter, S.L., Polígono industrial sector 14, C/ Pouet de Camilo nº2, 46394 Ribarroja del Turia, Valencia, España</div><div>07-06-00-1526</div></div>	Ca ²⁺	Mg ²⁺	Na ⁺	Cl ⁻	HCO ₃ ⁻	K ⁺	HPO ₄ ²⁻	mmol/l	1.25	0.6	140	115.9	30	4	1.2	<div><div><div>A 250 ml</div><div>B 4750 ml</div></div><div>phoXilium 1,2 mmol/l phosphate Phosphat fosfaat</div><div>C.N 664998.50H 8 470006 649985</div></div> <div><div>Read the package leaflet before use. Before use check for leaks. Use only if solution is clear and practically free from particles. For single use only. Discard any unused solution immediately after use. Not for direct infusion: mix both compartments before use. Read the package leaflet for shelf life of reconstituted product. Store between +4°C – +30°C. Do not refrigerate or freeze. UK: PL 00116/0708 IE: PA 2299/053/001 MT: MA 1277/03001</div><div>Consultar o folheto informativo antes de utilizar. Verificar fugas. Só utilizar se a solução estiver limpa e isenta de partículas visíveis. Para utilização única. Rejeitar qualquer solução não utilizada imediatamente após utilização. Não utilizar em perfusão direta. Misturar ambos os compartimentos antes de usar. Consultar o folheto informativo quanto ao prazo de validade do produto reconstituído. Conservar entre +4°C e +30°C. Não refrigerar ou congelar. Medicamento sujeito a receita médica restrita. 5192653 C.N 664998.50H Leer el prospecto antes de utilizar este medicamento. Compruebe si hay fugas. Utilizar solo si la solución está transparente y no se observa prácticamente ninguna partícula. Para un solo uso. Deseche toda solución que no se haya utilizado inmediatamente después de terminado su uso. No utilizar para infusión directa. Antes de usar, mezclar ambos compartimentos. Para conocer el periodo de validez del producto una vez reconstituido, leer el prospecto. Conservar a una temperatura entre 4°C y 30°C. No refrigerar o congelar. MEDICAMENTO SUJETO A PRESCRIPCIÓN MÉDICA. Use hospitalario.</div></div> <div><div>Petit compartiment A Kleine Kammer A Uit het kleine compartiment A: Eau pour préparations injectables, acide chlorhydrique (pour ajustement du pH) Wasser für Injektionszwecke, Salzsäure (zur Anpassung des pH-Werts) Water voor injecties, zoutzuur (voor pH-aanpassing).</div><div>Grand compartiment B Große Kammer B Uit het grote compartiment B: Eau pour préparations injectables, dioxyde de carbone (pour ajustement du pH) Wasser für Injektionszwecke, Kohlendioxid (zur Anpassung des pH-Werts) Water voor injecties, koolstofdioxide (voor pH-aanpassing).</div></div> <div><table><tr><th>Ca²⁺</th><th>Mg²⁺</th><th>Na⁺</th><th>Cl⁻</th><th>HCO₃⁻</th><th>K⁺</th><th>HPO₄²⁻</th></tr><tr><td>mmol/l</td><td>1,25</td><td>0,6</td><td>140</td><td>115,9</td><td>30</td><td>4</td><td>1,2</td></tr></table><div>Osmolarité théorique Theoretische Osmolarität Berekende osmolariteit: 293 mOsm/l</div></div> <div><div>Product No.: 113638 No. de lot Ch.-B. Lotnummer: A utiliser avant Verwendbar bis Uiterste gebruiksdatum: Titulaire Pharmazeutischer Unternehmer Farmaceutische vergunninghouder: Baxter Holding B.V., Kobaltweg 49, 3542CE Utrecht, Nederlande Nederland Pays-Bas</div><div>07-06-00-1465</div></div>		Ca ²⁺	Mg ²⁺	Na ⁺	Cl ⁻	HCO ₃ ⁻	K ⁺	HPO ₄ ²⁻	mmol/l	1,25	0,6	140	115,9	30	4	1,2
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